

Vermont State Hospital Policy		
VSH Waived Testing Policy		
	New	Effective date: 6.17.09
	INTERIM	Effective Date: 6.12.09
	Updated	Effective Date:
Reviewed by Steering Committee of Vermont State Hospital:		Date: 6.17.09
Approved by the Commissioner		Date: 6.17.09

I. Policy Statement

Vermont State Hospital (VSH) is fully committed to high standards of consumer safety as it relates to waived laboratory testing. The only waived testing procedure that VSH performs is glucose testing.

II. Purpose

This policy is established to ensure standards and practices are maintained as to the accuracy, reliability and timeliness of waived testing approved by the Department of Health and Human Services.

III. Definitions

- a. CLIA: Clinical Laboratory Improvements Amendments of 1988: When an individual other than a representative of the Clinical Laboratory performs a test or interprets the results of a test result, it is an activity that is regulated by CLIA.
- b. Waived Testing: Simple laboratory examinations and procedures that are cleared by the FDA for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

IV. Procedure

- a. **Certification**
 - i. VSH will have a current, valid CLIA certificate of waiver for the following testing: Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use
 - ii. The certificate of waiver will be renewed as directed, and
 - iii. The certificate of waiver will be displayed in the hallway near the Clinic on Dale 1.
- b. **Education and skill testing**
 - i. All direct care staff who have been designated to perform waived testing will be trained during orientation to perform these procedures.
 - ii. The direct care staff will demonstrate competency before performing the procedure on their own.
 - iii. Continued competency testing will be performed on an as needed basis, but at least annually.
 - iv. If a direct care staff has not completed a waived testing procedure within the last 6 months, the staff will demonstrate competency before performing the test.
 - v. Education and competency results will be current and maintained with the VSH Education and Training Department.
 - vi. All education and competency documentation will be readily available in the Education and Training Department.

- c. Process and results of testing
 - i. All waived tests will be performed according to procedure dictated by the VSH Education and Training Department.
 - ii. Questions or concerns regarding testing will be addressed by the appropriate supervisor, and the Education and Training Coordinator.
 - iii. Results of all waived tests will be documented and kept in the patient's medical record.
- d. Equipment performance evaluation.
 - i. Equipment utilized in waived testing (i.e., glucometer) will be maintained according to the manufacturer's manual, to include quality control checks.
 - ii. The manufacturer's manual will be kept in a centralized and easily accessible location.

V. References/Legal Authority

Joint Commission